REMARKS

Claims 1-18 are pending. Claims 10-16 and 18 have been withdrawn by the Examiner as being drawn to a nonelected invention. Claims 1-9 are newly canceled by Applicant. Claims 19-24 are newly added by Applicant. Claim 17 and withdrawn claims 10, 15, 16 and 18 are newly amended by Applicant. Support for the amendments can be found throughout the specification and in the claims as originally filed. No new matter has been entered.

Specifically, support for newly added claims 19-23 includes originally filed claims 1-9. Claims 17 is newly amended to change its dependency from newly canceled Claim 1, to newly added claims 19-24. Withdrawn method claims 10, 15, 16 and 18 are newly amended to change their dependency from newly canceled Claim 1, to newly added product claims 19-24.

Specification

The specification is objected to as containing browser executable codes (URLs). Accordingly, Applicant has replaced the disclosure of these URLs with non-executable names as indicated in the amendments to the specification.

35 U.S.C. § 112, 2nd Paragraph- Indefiniteness

Claims 2-6 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

Specifically, the office action indicates that claims 2-6 are indefinite because the claims recite the term "hypervariable regions", and then list the CDR1, CDR2, and CDR3, etc., as the regions themselves.

Further, the office action indicates that claims 4-6 are indefinite in their recitation of the phrase "direct equivalents thereof"

Applicant respectfully traverses. However, solely in the interest of advancing prosecution, Applicant has cancelled the instant claims without prejudice, rendering their rejection moot.

35 U.S.C. § 101

Claim 1 is rejected under 35 U.S.C. § 101 because the claim is directed to nonstatutory subject matter. Applicant has canceled claim 1, rendering its rejection moot.

35 USC § 102

Claims 1 and 17 are rejected under 35 USC § 102(b) as being unpatentable over Chen et al. (Nature 2000, 403:434-439).

Applicant respectfully traverses, but has canceled claim 1 without prejudice, solely in the interest of advancing prosecution, and amended the dependency of claim 17, drawn to a pharmaceutical composition, so that it depends from newly added claims 19-24.

35 USC § 103

Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Chen et al. (Nature 2000, 403:434-439) and further in view of Bendig *et al.* (1996) (5,558,864).

Applicant respectfully traverses, but has canceled claim 8 without prejudice, solely in the interest of advancing prosecution.

35 U.S.C. § 112, 1st Paragraph - Enablement

Claims 2-7 and 9 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement.

Applicant respectfully traverses, but has canceled Claims 2-7 and 9, without prejudice, solely in the interest of advancing prosecution.

The following comments are presented to the extent that the rejection of the instant claims relates to the newly added claims 19-24.

Newly added claims 19-21 are drawn to a Nogo_A623-640 binding molecule that comprises the heavy chain CDR regions of SEQ ID NOs: 8, 9 and 10, and the light chain CDR regions of SEQ ID NOs: 11, 12 and 13. Newly added claims 22-24 are drawn to a Nogo_A623-640 binding molecule comprising heavy chain CDR regions and light chain CDR regions that have at least 90% homology to SEQ ID NOs: 8, 9 and 10, and to SEQ ID NOs: 11, 12 and 13, respectively.

While not acquiescing to the assertion in the Office Action that the specification is not enabled for antibodies whose amino acid sequences deviate from the disclosed series of sequences SEQ ID NO:8, 9, and 10, and 11, 12, and 13, by as much as 50%, newly added claims 22-24 are drawn to Nogo_A623-640 binding molecules comprising CDR regions that have at least 90% homology to SEQ ID NOs: 8, 9 and 10, and to SEQ ID NOs: 11, 12 and 13. Applicant respectfully submits that newly added claims 19-24 are enabled and that no undue experimentation would be required to practice the claimed invention.

35 U.S.C. § 112, 1st Paragraph – Written Description

Claims 2-7 and 9 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement.

Applicant respectfully traverses the rejection, but has canceled Claims 2-7 and 9, without prejudice, solely in the interest of advancing prosecution.

The following comments are presented to the extent that the rejection of the instant claims may apply to the newly added claims 19-24.

Newly added claims 19-21 are drawn to a Nogo_A623-640 binding molecule that comprises the heavy chain CDR regions of SEQ ID NOs: 8, 9 and 10, and the light chain CDR regions of SEQ ID NOs: 11, 12 and 13. Newly added claims 22-24 are drawn to a Nogo_A623-640 binding molecule comprising heavy chain CDR regions and light chain CDR regions that have at least 90% homology to SEQ ID NOs: 8, 9 and 10, and to SEQ ID NOs: 11, 12 and 13, respectively.

To satisfy the written description requirement, patents must describe the technology that is

sought to be patented so as "to satisfy the inventor's obligation to disclose the technologic knowledge upon which the patent is based, and to demonstrate that the patentee was in possession of the invention that is claimed." Capon v. Eshhar, 418 F.3d 1349, 1357, 76 USPQ2d 1078, 1084 (Fed. Cir. 2005). The inquiry is primarily factual and depends on the nature of the invention and the amount of knowledge imparted to those skilled in the art by the disclosure (In re Wertheim, 541 F.2d at 262, 191 USPQ at 96).

The office action acknowledges that the instant specification shows support for antibody comprising SEQ ID NOs: 8, 9 10 and SEQ ID NOs: 11, 12 and 13. However, the office action states that the "description of one anti-Nogo antibody is not adequate written description of an entire genus of functionally equivalent peptide antibodies",

Reduction to practice of a single species encompassed within a genus is sufficient to support written description (Enzo Biochem, 323 F.3d at 966, 63 USPQ2d at 1615; Noelle v. Lederman, 355 F.3d 1343, 1350, 69 USPQ2d 1508, 1514 (Fed. Cir. 2004) (Fed. Cir. 2004)). By providing an example of the claimed Nogo_A623-640 binding molecule, i.e. antibody 3C7 in Examples 3-7 of the instant specification, and thus demonstrating reduction to practice, Applicant has not only met, but exceeded the written description requirements, according to *Faulkner v Inglas*, 448 F.3d 1357 07 (Fed. Cir. 2006). In *Faulkner v Inglas*, the court enunciated that examples are not necessary to support the adequacy of a written description, and further that the written description standards may be met even where actual reduction to practice of an invention is absent.

Further, the claim language is in accordance with the written description requirements as presented in the USPTO's training materials. There is actual reduction to practice of the recited Nogo_A623-640 binding molecule as evidenced by the disclosure of the production and characterization of the murine monoclonal antibody 11C7's binding the NogoA fragment starting at amino acid 623 and ending at amino acid 640 of the human NogoA amino acid sequence, see at least Working Examples 3 and 4. The specification indicates that the genus of proteins that must be variants of the recited Nogo_A623-640 binding molecule, and it does not have substantial variation since all variants must have at least 90% identity to the reference recited amino acid sequence. The single species disclosed is representative of the genus because all members have at least 90% structural identity with the recited CDR sequences of the reference Nogo_A623-640 binding

protein, and because procedures for making variants of the reference Nogo_A623-640 binding protein which have at least 90% identity to its recited amino acid sequence are conventional in the art. One of skill in the art would conclude that Applicant was in possession of the necessary common attributes possessed by the members of the genus of Nogo_A623-640 binding proteins encompassed by the instant claims.

The office action further states that "the specification does not teach functional or structural characteristics of all claimed antibody peptides". Applicant respectfully disagrees, noting that the claimed functional characteristic of binding Nogo_A623-640, and its structural basis, are disclosed in the specification, including as follows:

> "Amino acid sequence variants of a polypeptide according to the present invention, e.g. of a specified sequence, still have the ability to bind to human NogoA or human NiG or more preferably to Nogo_A623-640", emphasis added, paragraph 0052 of the instant specification, published as US20060183678,
>
> and is
>
> "...capable of binding the human NogoA, human NiG, human NiG-D20, or human Nogo_A623-640 with a dissociation constant <1000 nM and comprises a first antigen binding site comprising in sequence the hypervariable regions CDR1, CDR2, and CDR3, of which each of the hypervariable regions are at least 50%, preferably 80, 90, 95, 96, 97, 98, 99% homologous to their equivalent hypervariable regions CDR1-11C7 (SEQ ID NO: 8), CDR2-11C7 (SEQ ID NO: 9) and CDR3-11C7 (SEQ ID NO: 10); and a second antigen binding site comprising in sequence the hypervariable regions CDR1', CDR2', and CDR3', of which each of the hypervariable regions are at least 50%, preferably 80, 90, 95, 96, 97, 98, 99% homologous to their equivalent hypervariable regions CDR1'-11C7 (SEQ ID NO: 11), CDR2'-11C7 (SEQ ID NO: 12) and CDR3'-11C7 (SEQ ID NO: 13)", paragraphs 0041-43 of the instant specification, published as US20060183678,
>
> and
>
> "This dissociation constant may be conveniently tested in various assays including, for example, the biosensor affinity method described in the example 7. In addition, the binding and functional effect of the Binding Molecules may be shown in a bioassay, e.g. as described below", emphasis added, paragraph 44 of the instant specification, published as US20060183678, referring to the assays described in the Working Examples and in paragraphs 0092-0097, .

In addition to the disclosed function of binding human Nogo_A623-640 with a dissociation constant (Kd)<1000 nM, (paragraph 41 of the published specification), the claimed Nogo_A623-640 binding molecules are also disclosed as neutralizing NogoA as assayed by the regenerative sprouting and neurite outgrowth in the in vivo spinal cord injury model (paragraphs 0092-0097 of the published specification), and as exhibiting very good nerve repair activity as shown, for example, in the neurite outgrowth models (paragraphs 007, 0087, 0088 and 0129 of the published specification). The structure of the claimed Nogo_A623-640 binding molecules is also disclosed as being 90% homologous to the recited CDR regions, providing for changes in only a few amino acids at most, (paragraphs 0041-43 of the published specification).

Thus, the specification's disclosure of the above mentioned distinguishing functional and structural characteristics identifies the claimed genus of Nogo_A623-640 binding proteins with sufficient relevant identifying characteristics required to show that Applicant has possession of the claimed genus according to *Enzo Biochem, Inc. v. GenProbe Inc.,* 323 F.3d 956, 964 (Fed. Cir. 2002).

Conclusion

Applicant submits that all claims are allowable as written and respectfully request early favorable action by the Examiner. If the Examiner believes that a telephone conversation with Applicant's attorney/agent would expedite prosecution of this application, the Examiner is cordially invited to call the undersigned attorney/agent of record.

Dated: February 27, 2009

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